

## REMARKS

### Summary of Office Action

Claims 29-50 are pending in this application.

The Examiner finally rejected claims 29, 31, 33, 34, 45, 47, 49, and 50 under 35 U.S.C. § 103(a) as being obvious from Forsberg et al. U.S. Patent No. 6,807,797 (hereinafter "Forsberg") in view of Tischlinger U.S. Patent No. 4,059,109 (hereinafter "Tischlinger").

Claims 37-39, 41, 43, and 44 were finally rejected under 35 U.S.C. § 103(a) as being obvious from Forsberg and Tischlinger in view of Odell et al. U.S. Patent No. 6,263,641 (hereinafter "Odell").

Dependent claims 30, 40, and 46 were finally rejected under 35 U.S.C. § 103(a) as being obvious from Forsberg/Tischlinger/Odell in view of Geprägs U.S. Patent No. 4,781,701 (hereinafter "Geprägs").

And claims 32, 34-36, 42, 45, and 47-50 were finally rejected under 35 U.S.C. § 103(a) as being obvious from Tanaka et al. U.S. Patent No. 5,716,339 (hereinafter "Tanaka").

### Summary of Applicants' Reply

Applicants submit concurrently herewith a Request For Continued Examination under 37 C.F.R. § 1.114.

Applicants have amended claims 29, 39, and 45 to more particularly point out and distinctly claim the subject matter that applicants regard as the invention.

No new matter has been added.

Reconsideration of this application in view of the amendments and following remarks is respectfully requested.

Rejections of Claims 29, 31, 33, 34, 45, 47, 49, and 50 Under 35 U.S.C. § 103(a)

Claims 29, 31, 33, 34, 45, 47, 49, and 50 have been rejected under 35 U.S.C. § 103(a) as being obvious from Forsberg in view of Tischlinger.

These rejections are respectfully traversed.

Independent Claim 29

Independent claim 29 has been amended to require the moveable sealing plug to open a flow path through the seal structure around the outermost periphery of the sealing plug. Support for this amendment is found, *e.g.*, in FIG. 9 (the elected species, *see* applicants' November 7, 2005 Reply To Office Action) and in the specification (*see, e.g.*, paragraph 44 on page 11: "grooves 168 create a flowpath ... through which liquid ... can bypass seal plug 166 when the plug 166 is moved forwardly").

In Forsberg's method, a middle piston 3 is inserted into barrel 1. Piston 3 has no moveable sealing plug and has no need for such a sealing plug because barrel 1 has an enlarged bypass 4 area that allows a solvent in rear chamber 6 to flow around piston 3 and into front chamber 5 when piston 3 is moved into that area.

Tischlinger has a rupturable diaphragm assembly 18 positioned within barrel 12 between the ends of the barrel. Diaphragm assembly 18 has a needle 100, a central opening 94, and a flexible wall 96 initially sealing the central opening. Deflection of the wall 96 causes the needle to puncture the wall, opening a flow path through needle 100.

Tischlinger's wall 96 is plainly not a sealing plug and there is no flow path around the outermost periphery of wall 96.

In sum, the combination of Forsberg and Tischlinger does not result in applicants' invention as defined in amended independent claim 29 and, therefore, claim 29 is not obvious from that combination and should be allowable.

For at least these reasons, dependent claims 31, 33, and 34, which depend either directly or indirectly from independent claim 29, should also be allowable (*i.e.*, dependent claims are allowable if their independent claim is allowable).

#### Independent Claim 45

Independent claim 45 has been amended to require the inserted seal structure to have a slidable sealing plug operative to slide from a sealing position to a by-pass area within the seal structure to open a flow path through the seal structure. Support for this amendment is found, *e.g.*, in FIG. 9 (the elected species) and in the specification (*see, e.g.*, page 11, paragraph 44: "the sealing plug 166 may easily slide within outer sealing object 180" and the "sealing plug 166 preferably includes a plurality of circumferential grooves 186 to ... facilitate sliding action of the plug 166").

Again, in Forsberg's method, there is no moveable sealing plug, and Tischlinger's wall 96 is not a sealing plug and does not "slide" from a sealing position to a by-pass area within the seal structure.

Claim 45 is therefore not obvious from the combination of Forsberg and Tischlinger and should thus be allowable.

Dependent claims 47, 49, and 50, which depend from independent claim 45, should also be allowable (*i.e.*, dependent claims are allowable if their independent claim is allowable).

Accordingly, applicants respectfully request that the rejections of claims 29, 31, 33, 34, 45, 47, 49, and 50 under 35 U.S.C. § 103(a) be withdrawn.

Rejections of Claims 37-39, 41, 43, and 44 Under 35 U.S.C. § 103(a)

Claims 37-39, 41, 43, and 44 have been rejected under 35 U.S.C. § 103(a) as being obvious from Forsberg and Tischlinger in view of Odell.

These rejections are respectfully traversed.

For at least the same reasons as discussed above regarding independent claim 29, dependent claims 37 and 38, which depend directly and indirectly from claim 29, respectively, should also be allowable (*i.e.*, dependent claims are allowable if their independent claim is allowable).

Independent Claim 39

Independent claim 39 has been amended to require the inserted seal structure to be needleless. Support for this amendment is plainly evident from FIG. 9 (*see* sealing structure 360, which comprises outer sealing member 380, filter 164, by-pass zone 165, and movable sealing plug 166; *compare with* the seal structures shown in FIGS. 8A and 8B which have seal membrane 226, pointed members 228, and no inner plug).

As discussed above, Forsberg's method has no moveable sealing plug, and Tischlinger's rupturable diaphragm assembly 18 has a needle 100 to puncture flexible wall 96.

Odell purportedly discloses methods of manufacturing drug delivery and drug container devices in clean, substantially particulate-free areas and, accordingly, does not make up for the deficiencies of Forsberg and Tischlinger.

The combination of Forsberg, Tischlinger, and Odell therefore does not render amended claim 39 obvious and, therefore, claim 39 should be allowable.

For at least these reasons, dependent claims 41, 43, and 44, which depend from independent claim 39, should also be allowable (*i.e.*, dependent claims are allowable if their independent claim is allowable).

Accordingly, applicants respectfully request that the rejections of claims 37-39, 41, 43, and 44 under 35 U.S.C. § 103(a) be withdrawn.

Rejections of Claims 30, 32, 34-36, 40, 42, and 45-50 Under 35 U.S.C. § 103(a)

Claims 30, 40, and 46 have been rejected under 35 U.S.C. § 103(a) as being obvious from Forsberg/Tischlinger/Odell in view of Geprägs. Claims 32, 34-36, 42, 45, and 47-50 have been rejected under 35 U.S.C. § 103(a) as being obvious from Tanaka.

These rejections are respectfully traversed.

Geprägs was cited because it purportedly discloses a front syringe barrel with a tapered flow path.

Tanaka was cited because it purportedly discloses a rear chamber filled first with a substance and a front chamber filled next with a dry medication.

Accordingly, neither Geprägs nor Tanaka makes up for the deficiencies of Forsberg and Tischlinger as discussed above with respect to amended independent claims 29, 39, and 45.

Thus, any combination of Forsberg, Tischlinger, Odell, Geprägs, and Tanaka does not render obvious independent claims 29, 39, or 45.

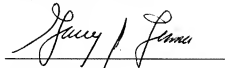
For at least these reasons, dependent claims 30, 32, 34-36, 40, 42, and 46-50, which depend directly or indirectly from one of claims 29, 39, or 45, should also be allowable (*i.e.*, dependent claims are allowable if their independent claim is allowable).

Accordingly, applicants respectfully request that the rejections of claims 30, 32, 34-36, 40, 42, and 45-50 under 35 U.S.C. § 103(a) be withdrawn.

#### Conclusion

The foregoing demonstrates that claims 29-50 are allowable. This application is therefore in condition for allowance. Reconsideration and allowance are accordingly respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Garry J. Tuma", is written over a horizontal line.

Garry J. Tuma  
Registration No. 40,210  
Attorney for Applicants

JONES DAY  
Customer No. 20583  
222 East 41st Street  
New York, New York 10017  
(212) 326-3939